UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION ***APPLIES TO ALL CASES***	**Case No. 1:17-MD-2804** **Hon. Dan A. Polster** **ORAL ARGUMENT REQUESTED**

MEMORANDUM IN SUPPORT OF MANUFACTURERS' JOINT MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' RICO, OCPA, AND CONSPIRACY CLAIMS

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INTRODUCTION

Plaintiffs offer unfounded and untenable theories under RICO, the Ohio Corrupt Practices Act (OCPA), and common-law conspiracy.[1] Manufacturers compete with one another for sales. Nonetheless, Plaintiffs allege two racketeering "enterprises," each with the supposed common purpose of marketing opioid medications for the long-term treatment of chronic pain—a use approved by the FDA. But Plaintiffs cannot establish the central feature of a RICO/OCPA enterprise—***coordination*** to achieve an ***unlawful common purpose***. Because Plaintiffs have no evidence of an ***agreement*** to ***unlawfully harm another***, their civil conspiracy claim fails as well. Similar marketing efforts do not prove that the Manufactures coordinated or agreed on their efforts. At most, the marketing shows that certain Manufacturers engaged in parallel yet ***independent*** business activities in furtherance of their own self-interest. And there is nothing unlawful about marketing an FDA-approved medication for its FDA-approved uses. Such marketing can provide education to healthcare professionals about an important treatment for chronic pain. As the FDA recently cautioned, "[i]nadequately treated chronic pain has consequences."[2] To varying degrees, Manufacturers have simply sought to educate healthcare professionals and patients about an important tool in the treatment of chronic pain.

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[1] The Actavis Generic Defendants are not named as defendants with respect to Plaintiffs' RICO and OCPA Marketing Enterprise claims (Counts I and III). Further, Plaintiffs group Noramco together with J&J and its other affiliated entities, all Marketing Defendants, or all Defendants collectively. For this reason, Noramco joins this motion even though it never manufactured, packaged, branded, marketed, promoted, distributed or sold the finished prescription medications at issue in this litigation. Indeed, Noramco is an active pharmaceutical ingredient supplier, and not a finished drug product manufacturer. As such there is ***no evidence*** that Noramco, an active pharmaceutical ingredient supplier, engaged in ***any*** wrongful conduct that might give rise to liability (*See* Noramco's Memorandum in Support of Motion for Judgment on the Pleadings Or, in the Alternative, Summary Judgment), let alone conduct that could impose liability under RICO, the OCPA or any civil conspiracy laws.

[2] Ex. 1, FDA Briefing Document, Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee, June 11-12, 2019, at 10.

Undaunted, Plaintiffs charge ahead with the claim that Manufacturers carried out a "RICO Marketing Enterprise" by associating with healthcare organizations and "key opinion leaders" (KOLs)—respected doctors and experts in their fields who in this instance did research, wrote articles, and spoke to other healthcare professionals about advances in pain management, including prescription opioids and other treatments. According to Plaintiffs, certain of the Manufacturers controlled these third parties through sponsorships, contributions, and consulting payments. Yet, a Manufacturer's sponsorship of doctors or healthcare organizations who conduct research, educate, and advocate about pain management, does not mean those third parties formed a coordinated, continuing unit with the Manufacturer. Plaintiffs' claims that the Manufacturers' financial contributions to of third parties is somehow evidence of nefarious undue influence, racketeering, and conspiracy is nothing more than speculation. Plaintiffs also claim there was a ***second*** conspiracy—a separate "Supply Chain Enterprise" among certain Manufacturers and Distributors to increase the quota and volume of U.S. opioid sales. Yet, Plaintiffs have no evidence of unlawful coordination between the Distributors and Manufacturers either.

Plaintiffs had the opportunity to explore their theory that certain Manufacturers directed and controlled KOLs to advance the alleged racketeering scheme. Yet, with one exception, Plaintiffs decided they would not get sworn testimony from the doctors who were allegedly key to this racketeering scheme, and Plaintiffs ***do not intend to rely on those KOLs at trial***.[3] The one exception? Dr. Russell Portenoy, who gave Plaintiffs a Declaration stating that he was ***not influenced*** by any of the consulting fees or honoraria he has received from pharmaceutical companies.[4] It is thus no surprise Plaintiffs decided to abandon their KOL discovery. Plaintiffs

[3] Ex. 2, Pls.' Feb. 14, 2019 Ltr. to D. Cohen.
[4] Ex. 3, Decl. of R. Portenoy, M.D., ¶ 35; Ex. 4, Dep. of R. Portenoy at 398:21–399:2.

also had the opportunity to pursue discovery of the healthcare organizations alleged to be under the direction and control of certain Manufacturers. But that discovery failed to turn up any evidence that Manufacturers directed and controlled those organizations.

Magistrate Judge Ruiz and the Court gave Plaintiffs an opportunity to develop a record that would "describe the exact inner workings" of these alleged enterprises. R & R (Dkt. 1025) at 38. But after extensive and sweeping discovery, Plaintiffs have no evidence sufficient to support their racketeering and conspiracy claims. There is ***no evidence*** of an enterprise, let alone ***two enterprises***, among the Manufacturers: no agreements, no "alliances," no handshakes, not even a nod and a wink. Why? Because the alleged enterprises do not exist.

Plaintiffs' inability to prove an enterprise or conspiracy should end the inquiry. But the racketeering allegations raise additional causation issues. Plaintiffs' claimed injuries are so indirect that the RICO and OCPA claims cannot stand, and their expert did not even try to measure whether the alleged actions of the KOLs and healthcare organizations impacted Plaintiffs. At a minimum, though, Plaintiffs cannot maintain racketeering claims for "branded" advertising that promotes one brand at the expense of others. By its very nature, this marketing is a competitive action to advance an individual Manufacturer's self-interest. Finally, Plaintiffs have no claims for damages that resulted from third-party personal injuries. Those damages, even if they existed, are not an injury to "business or property" and thus not compensable under RICO.

Plaintiffs failed to create a genuine issue of material fact as to whether the Manufacturers violated RICO or the OCPA, participated in a conspiracy, or caused a RICO/OCPA injury. The Court should enter judgment in favor of the Manufacturers on Counts I, II, III, IV, and XI.

FACTS

A. The Manufacturers

Despite receiving millions of pages of documents from the Manufacturers and taking hundreds of depositions of current and former employees, Plaintiffs have identified no evidence of a coordinated scheme among the Manufacturers. And there is certainly no evidence of any conspiracy or agreement that involves generic Manufacturers who do not promote their medicines. Instead, the scores of strategic marketing plans and the sales representative compensation systems criticized by Plaintiffs compel the same conclusion: the Manufacturers were rivals who tried to gain market share for their products at the expense of competitors.

The Manufacturers develop, manufacture, and sell prescription opioid medications. They compete with each other and with non-defendant companies to provide effective pain management therapy to patients in need. Some promote their medicines to physicians; others, like generic Manufacturers, do not. During the time period relevant to Plaintiffs' claims (2012-2017)[5] and before, there were many different formulations of FDA-approved opioid medications, including immediate release (IR) or extended release/long-acting (ER/LA) tablets, transdermal patches, transmucosal lozenges, and more. These products had different features, benefits, and risks, and in some cases different FDA-approved uses ("indications"). For example, Actiq is a transmucosal lozenge indicated for breakthrough pain in cancer patients.[6] Duragesic is a transdermal patch that patients wear for seventy-two hours.[7] OxyContin is an oral ER/LA tablet that comes in a variety of doses, from 5mg to 80mg; the FDA has approved OxyContin and Duragesic to treat "pain severe

[5] For the reasons in the Defendants' motion for partial summary judgment on statute of limitations grounds, Plaintiffs cannot pursue claims for conduct that occurred before 2012, and therefore have to show that the alleged "enterprises" existed within the limitations period. *See* Mnfrs.' Br. Mot. Summ. J. re: Statutes of Limitations.
[6] Ex. 5, Actiq Prescribing Information.
[7] Ex. 6, Duragesic Prescribing Information.

enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[8]

During different time periods, certain individual Manufacturers marketed their products' differentiating features, and to varying degrees, also to educate healthcare professionals more generally about the need to address what the FDA has identified as the "serious and growing public health problem" of chronic pain,[9] which certain of these and other products at issue here were indicated to treat. The Manufacturers' marketing, to the extent they engaged in it, also reflected innovations in the prescription opioid market over time.[10] Manufacturers also competed on price and for favorable placement on insurance formularies.[11] In other instances, a company might choose to change its marketing for products facing competition from generic formulations, for the simple reason that a company does not make sales if generic substitution laws result in the patient receiving a generic formulation made by a competitor.[12] And generic manufacturers (like the Actavis Generic Defendants), which do not market or promote the safety or efficacy of their medicines, sold their medicines after the corresponding brand market had been created.

[8] Ex. 7, OxyContin Prescribing Information; Ex. 6, Duragesic Prescribing Information.
[9] Ex. 8, FDA Resp. to PROP Petition, at 2.
[10] For example, in promotional pieces, Purdue informed healthcare professionals, that "OxyContin was reformulated and in 2013 became the first opioid with FDA-approved labeling describing abuse-deterrent characteristics." *See* Ex. 9, PPLP003277791-003277805. Another promotion informed healthcare professionals that OxyContin's flexible dosing and ER/LA formulation allowed patients to use fewer tablets monthly than those treating with Vicodin, Tylenol with codeine, Percocet, or Norco. Ex. 10, PPLP003276691-003276694.
[11] Ex. 11, Dep. of Stephen Becker, at 63:7–64:10; Ex. 12, Dep. of Andrew Boyer, at 206:14–207:5; Ex. 13, Dep. of Michael Dorsey, at 66:24–68:21; Ex. 14, Dep. of Kate Neely, at 134:20–136:5; Ex. 15, Dep. of Bonnie New, at 58:4–58:23; Ex. 16, Dep. of George Stevenson, at 151:18–154:3, 158:16–159:4; Ex. 17, Dep. of Scott Tomsky, at 153:14–154:16.
[12] *See* Ex. 18, Dep. of Bruce Ritchie, at 39:22–40:21; Ex. 19, Dep. of Larry Romaine, 291:9–292:22.

B. Key Opinion Leaders

Key Opinion Leaders, who consult with some of the Manufacturers, play an important role in research and continuing medical education (CME). Pharmaceutical and medical device companies routinely rely on KOLs for this support. Dr. Joel Saper, a third-party neurologist deposed by Plaintiffs, testified that it is important for pharmaceutical companies to "consult with top experts in their fields"—*i.e.*, KOLs. Dr. Saper acknowledged "it would be a problem or it could be ***detrimental to patients*** if pharmaceutical companies did not consult with experts in their fields."[13]

KOLs may receive research grants or honoraria in exchange for their expert consulting. As KOL Dr. Russell Portenoy explained, these financial arrangements are "very common for successful physician academicians."[14] For years, KOLs and others in the public health field have disclosed financial support received from outside sources, as encouraged or required by the American Medical Association,[15] the Accreditation Council for Continuing Medical Education (ACCME),[16] academic institutions, hospitals, medical journals, and the Code adopted by Pharmaceutical Research and Manufacturers of America ("PhRMA"), a pharmaceutical manufacturer trade association.[17] Since August 1, 2013, the Physicians Payments Sunshine Act

[13] Ex. 20, Dep. of J. Saper, M.D., at 126:21–127:12
[14] Ex. 21, Decl. of Russell K. Portenoy, M.D. ¶ 21.
[15] *See* Ex. 22, AMA Opinion 8.061 (requiring disclosure of financial support or conflicts of interest in connection with conferences or meetings); Ex. 23, AMA Code of Medical Ethics 9.6.2 (governing gifts from the industry to physicians); Ex. 24, AMA Opinion 9.0115 (Financial Relationships with Industry in CME).
[16] Ex. 25, Preamble to the ACCME Standards for Commercial Support; Ex. 26, Standards for Commercial Support, Accreditation Council for Continuing Medical Education (2004).
[17] Ex. 27, Code on Interactions with Healthcare Professionals, PhRMA (2009).

has required pharmaceutical and medical device manufacturers to track and report payments and items of value given to physicians and teaching hospitals.[18]

Plaintiffs claim four KOLs were part of the alleged "Opioid Marketing Enterprise": Drs. Russell Portenoy, Lynn Webster, Perry Fine, and Scott Fishman. Each KOL was a defendant in certain cases in the MDL and state courts. The MDL Plaintiffs quietly settled with these KOLs in 2018. Plaintiffs then sat for four-hour proffers with Drs. Fine, Fishman, and Webster, but did not depose them.[19] As Plaintiffs informed Special Master Cohen, they "do not intend to rely on Drs. Fine, Fishman nor Webster at trial."[20] On the other hand, Dr. Portenoy, a renowned neurologist and pain expert, provided a Declaration for Plaintiffs. He acknowledged receiving funding from Manufacturers over the course of his career, but declared under penalty of perjury, "***I personally was never influenced to say things I did not believe***."[21]

C. Healthcare Organizations

Plaintiffs contend certain of the Manufacturers directed and controlled the activities of a number of healthcare organizations: American Geriatrics Society, Federation of State Medical Boards, American Pain Society, American Academy of Pain Medicine, United States Pain Foundation, and American Pain Foundation. Healthcare organizations engage in valuable research, education, policy-making, and patient advocacy.

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[18] Ex. 28, Sunshine Act: Physician Financial Transparency Reports, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/specialty%20group/washington/sunshine-act-brochure.pdf.

[19] Dr. Portenoy has not yet been deposed in the MDL as the result of a prolonged discovery dispute relating to the untimely disclosure of his cooperation agreement with Plaintiffs. On April 26, 2019, the Court ordered that Dr. Portenoy's deposition could proceed at Plaintiffs' expense (Dkt. 1577), and Defendants intend to depose Dr. Portenoy in the coming weeks. Defendants further reserve the right to depose any other KOL should Plaintiffs change their position that they "do not intend" to rely on these individuals' testimony at trial.

[20] Ex. 2, Feb. 14, 2019 Ltr. at 2.

[21] Ex. 21, Decl. of R. Portenoy, M.D. ¶¶ 21, 35.

The American Geriatric Society, founded in 1942, is a not-for-profit society of healthcare professionals dedicated to improving the health, independence, and quality of life of older people.[22] The Federation of State Medical Boards, founded in 1912, represents the seventy state medical and osteopathic regulatory boards. It has responsibility for the licensing, discipline, and regulation of healthcare professionals.[23] The American Pain Society is a multidisciplinary community of "scientists, clinicians, and other professionals who work together to educate about pain, transform public policy, and reduce pain-related suffering."[24] The American Academy of Pain Medicine advances and promotes the full spectrum of multidisciplinary pain care, education, advocacy, and research.[25] The United States Pain Foundation educates, empowers, connects, and advocates for people living with chronic conditions that cause pain. It was "created by people with pain, for people with pain."[26] The American Pain Foundation (APF) was created "for the purpose of responding to the need for public education and advocacy about pain."[27]

Although Plaintiffs alleged these healthcare organizations acted at the direction and control of certain Manufacturers, as with the KOLs, Plaintiffs and their experts relied entirely on contributions to these third parties as a proxy for control—with much of that funding occurring before 2012.[28] Moreover, many Manufacturers had medical education grant policies that

[22] Ex. 29, https://www.americangeriatrics.org/about-us/who-we-are
[23] Ex. 30, https://www.fsmb.org/about-fsmb/
[24] Ex. 31, http://americanpainsociety.org/about-us/overview
[25] Ex. 32, ttps://painmed.org/membership-in-aapm
[26] Ex. 33, https://uspainfoundation.org/about-us/our-team/
[27] Ex. 21, Decl. of R. Portenoy, M.D. ¶ 38.
[28] *See, e.g.*, Ex. 34, Rep. of Anna Lembke, M.D., Appendix II (discussing Manufacturers' funding of University of Wisconsin Pain and Policy Study Group from 1996 – 2011); Ex. 35, Rep. of David S. Egilman, Opinion 7.26 (opining on Endo's funding of alleged "Front Groups" in 2004); Ex. 36, Rep. of Matthew Perri III at ¶ 70 n.116 (discussing Manufacturers' funding of health advocacy groups, citing to several documents from before 2012); Ex. 37, Rep. of David Kessler, M.D. at 298-302 (discussing Manufacturers' funding of the American Pain Society in the same years as certain news bulletins or guidelines, published in 1997, 2001, and 2002).

specifically prohibited the Manufacturer from having any control over the content of organizations' independent education activity.[29]

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). "A party may use a summary judgment motion to challenge the sufficiency of his opponent's evidence—essentially, to challenge his opponent to 'put up or shut up.'" *Snyder v. Ohio Dep't of Rehab. & Correction*, 702 F. App'x 341, 342 (6th Cir. 2017) (internal quotation mark omitted). "Unless the non-movant produces evidence which would allow a reasonable jury to return a verdict for him, the court must grant the motion." *Id.* at 342–43.

ARGUMENT

I. THERE IS NO EVIDENCE OF AN ENTERPRISE.

RICO and OCPA require Plaintiffs to provide evidence that the Manufacturers participated in an "enterprise" through a pattern of racketeering. *See* 18 U.S.C. § 1962(c); OHIO REV. CODE § 2923.32(A)(1). Each defendant "must participate in the operation or management of the enterprise itself" and "be separate and distinct from the enterprise." *Richmond v. Nationwide Cassel L.P.*, 52 F.3d 640, 646 (7th Cir. 1995) (internal citations omitted). In each of their RICO claims, Plaintiffs allege that the enterprises were "associations in fact," rather than formal legal entities. This requires Plaintiffs to provide "***evidence*** of an ongoing organization" and "***evidence*** that the various associates function as a continuing unit." *Boyle v. United States*, 556 U.S. 938, 944–45 (2009) (emphases added). To satisfy this burden, Plaintiffs must produce evidence of a common purpose and relationships among those associated with the enterprise. *Id.* at 946.

[29] *E.g.*, Ex. 38, TEVA_MDL_A_00560932–35; Ex. 39, PPLP003472752–53.

Plaintiffs have to show more than "hypothetical relationships." *Browning v. Flexsteel Indus., Inc.*, 955 F. Supp. 2d 900, 912 (N.D. Ind. 2013). To prove the necessary "common purpose" and "relationships," there must be concrete evidence that the associates of the enterprise "associated together for a common purpose ***of engaging in a course of unlawful conduct***." *Robins v. Glob. Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 653 (N.D. Ohio 2012) (Polster, J.). Indeed, this Court has correctly recognized that "[r]outine business relationships, without more, are insufficient to establish a RICO claim." *Id.* at 653; *accord Gomez v. Guthy-Renker, LLC*, No. 14-1425, 2015 WL 4270042, at *8–9 (C.D. Cal. July 13, 2015). Plaintiffs must also show more than just a "similarity of goals and methods," *Libertad v. Welch*, 53 F.3d 428, 443 (1st Cir. 1995), or a "commonality of motive." *Gov't Empls. Ins. Co. v. Analgesic Healthcare, Inc.*, No. 16-11970, 2017 WL 1164496, at *3 (D. Mass. Mar. 28, 2017) (quoting *In re Lupron Mktg. & Sales Practices Litig.*, 395 F. Supp. 2d 148, 173 (D. Mass. 2003)). Rather, Plaintiffs have to show "***collaborative, coordinated effort*** to accomplish a truly common end that could not be as effectively pursued individually." *Browning*, 955 F. Supp. at 912 (emphasis added). If the evidence does not "suggest a group of persons acting together," there is no enterprise. *Rao v. BP Prods. N. Am., Inc.*, 589 F.3d 389, 400 (7th Cir. 2009).

The fundamental question for the Court, then, is whether Plaintiffs have legally sufficient evidence of anything "more" than routine, separate, bilateral business relationships among the Manufacturers, Distributors, KOLs, and healthcare organizations alleged to be associates in these "enterprises." Plaintiffs do not. When the Court allowed Plaintiffs' racketeering allegations to progress past the pleadings stage, the Court recognized that "discovery may yield no fruit." R&R 38. This has proven prophetic: despite taking discovery of nearly unprecedented scope and volume, there is ***no evidence***, let alone legally sufficient evidence, of either "enterprise." Plaintiffs

cannot show that the alleged "associates" coordinated their activities, and they cannot show that the associates shared an unlawful purpose.

A. There Is No Evidence of a "RICO Marketing Enterprise."

Plaintiffs envision a "hub-and-spoke" "RICO Marketing Enterprise"—in which each KOL and healthcare organization is a "spoke" extending from a "hub" comprised of certain Manufacturers—that sought to "alter the medical community's prescribing practices." R&R at 37. But there is no evidence of a "hub," let alone a hub that controlled or coordinated the "spokes."

1. There Is No Evidence the Manufacturers Coordinated with Each Other as a "Hub."

Plaintiffs cannot prove that the Manufacturers coordinated and formed a "hub" at the center of the alleged enterprise. *See, e.g.*, *Rao*, 589 F.3d at 400. Plaintiffs' allegations amount to nothing more than a claim that each member of the same industry independently sought to market its products for their lawful and intended uses. But that is normal, competitive business behavior, true of every industry. That goal is not unlawful or fraudulent, *Robins*, 838 F. Supp. 2d at 653, and it does not show coordination. *See Gov't Emps. Ins. Co.*, 2017 WL 1164496 at *3 (explaining that without evidence of coordination, "any group of persons sharing a common occupation, *e.g.*, urologists and lawyers, and a similar motive, *e.g.*, greed, could be held to constitute a RICO enterprise" (quoting *In re Lupron Mktg. & Sales Practices Litig.*, 395 F. Supp. 2d at 174)). It is lawful for the Manufacturers to sell their products for FDA-approved uses. The FDA continues to approve prescription opioids as safe and effective and authorizes their sale in the United States. It is also lawful for a manufacturer to gain sales, whether from a competitor or otherwise, and educate healthcare professionals about the benefits and risks of a prescription medication.

At most, Plaintiffs can show only that certain Manufacturers engaged in independent, rational, and market-driven decision-making. Plaintiffs have no evidence of "alliances" or

"strategic business discussions between high-level executives." R&R at 37. Just the opposite: the evidence demonstrates the Manufacturers "did not collaborate" about "sales, marketing [or] distribution."[30] When asked whether Purdue coordinated "unbranded" promotional efforts with Endo, Purdue's 30(b)(6) witness testified, "I'm not aware of working with Endo, for example, to expand the opioid market."[31] Similarly, the witness did not recall coordinating with other Manufacturers to provide third-party financial support.[32] Manufacturers did not collectively agree on which KOLs to "support," or jointly track the "reputation" of particular KOLs. Instead, the Manufacturers ***competed*** over contracts with KOLs who could provide "unfiltered feedback."[33]

The competitive nature of Manufacturers' relationships, as well as the restrictions imposed by antitrust laws, constrained communications among the Manufacturers, but certain lawful communications occurred. For example, some Manufacturers occasionally communicated about industry-wide topics, generally during meetings of trade associations such as the Pain Care Forum ("PCF"). But "[p]articipation in trade organizations provides no indication of" a RICO violation. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1295–96 (11th Cir. 2010). And in any event, Plaintiffs understandably do not claim PCF is part of any RICO enterprise. Meetings of the PCF included members such as The Partnership at Drugfree.org, an organization that helps parents prevent drug and alcohol abuse.[34] It is implausible to speculate that such a diverse trade association—with members holding competing viewpoints and policies—would harbor and

[30] Ex. 40, Dep. of Brian Lortie at 447:2–16, 458:14–23, 516:4–16.
[31] Ex. 41, Dep. of Alan Must (Purdue 30(b)(6)) at 185.
[32] *Id.* at 195–96.
[33] Ex. 42, Dep. of Linda Kirlinski at 552:9–554:18; Ex. 43, Dep. of Bruce Moskovitz at 262:20–263:12.
[34] Ex. 44, Dep of Burt Rosen at 311:14–312:19, 313:2–314:13; *accord* Ex. 45, Dep. of Brian Munroe at 422:1–424:19; Ex. 40, Dep. of Brian Lortie at 67:15–68:12; Ex. 46, Dep. of J. Adams at 63:15–18.

nurture a RICO marketing enterprise.[35] There certainly is no evidence to support that fanciful theory.

Even if Plaintiffs could show that: (1) each Manufacturer wanted to increase sales of its prescription opioids; and (2) each Manufacturer provided financial support to KOLs and/or healthcare organizations, that would merely establish parallel conduct, not coordination. Proof only that "competitors engage in similar behavior and are aware of each other's behavior," including funding and participating in the same trade associations, is not enough to create a jury question on the existence of an enterprise. *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1069 (11th Cir. 2017). If it were, "competitors who independently engaged in similar types of transactions with the same firm could be considered associates in a common enterprise." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 375 (3d Cir. 2010). Permitting a racketeering claim to proceed on this record is unsupportable under prevailing law, and would radically extend RICO and OCPA to reach parallel conduct of competitors absent any evidence of coordination.

2. There Is No Evidence the Manufacturers "Controlled," "Directed," or "Coordinated" the Third Parties' Activities.

Plaintiffs also cannot establish the necessary connections between this alleged Manufacturer "hub" and the third-party "spokes." Initially, Plaintiffs do not allege, and have not produced any evidence, that the KOLs and Front Groups shared the Manufacturers' alleged goal of marketing prescription opioids. That failure alone sinks the supposed marketing enterprise.

More fundamentally, the alleged marketing enterprise hinges on a simple but dangerous false premise: that contributions or consulting fees to third parties, without more, entitle Plaintiffs

[35] Other members of the PCF included the American Society of Anesthesiologists, the Amputee Coalition, the DC Pediatric Palliative Care Collaboration, the Harm Reduction Coalition, the Hematology/Oncology Pharmacy Association, the Hospice and Palliative Nurses Association, the National Association of Directors of Nursing Administration, and the Oncology Nursing Society. Ex. 47, JAN-MS-00992023.

to a jury trial on their racketeering claims. These payments are entirely lawful, common in the pharmaceutical industry, and nothing more than "routine business relationships." *Robins*, 838 F. Supp. 2d at 653. The third parties maintained their independence and control; they were free to say and publish whatever they chose. And that is exactly what they did. They published what they believed to be accurate statements based on the science of pain management at the time.

To this day, Plaintiffs have not uncovered any evidence to support their bare allegations that any Manufacturer "directed" or "controlled" these third parties. Plaintiffs cut a deal with the KOLs, settling in exchange for the opportunity to get secret proffers. With the exception of Dr. Portenoy, however, Plaintiffs did not take additional discovery of the KOLs in the MDL. Plaintiffs also had the benefit of the secret proffers and discovery taken of these KOLs in the *State of Oklahoma* opioid litigation, which established:

- Dr. Lynn Webster did not believe the Manufacturers "used my influence to increase prescriptions of their drugs." He identified no instance where a pharmaceutical company "influenced the content of any opinions or publications" of third party pain advocacy or physician advocacy groups.[36]

- Dr. Scott Fishman could not identify "any instance where a pharmaceutical company somehow controlled an opinion I had given to a particular pain-management-related issue." He commented that "pharmaceutical companies . . . [did not] ever control the content of any publication or speech that I have ever been involved with," and if "I disagreed with anything that a pharmaceutical company may have asked of me with respect to a presentation . . . I would have said, 'I'm not going to include that in my presentation.'"[37]

Dr. Russell Portenoy's testimony in the *Oklahoma* case was consistent with the Declaration he provided Plaintiffs. He acknowledged that he received funding from Manufacturers and others, but as he testified, this never "influenced anything I said with respect to saying something I didn't believe was accurate."[38] Similarly, in this case Dr. Portenoy declared, "I personally was ***never***

[36] Ex. 48, Dep. of Lynn Webster at 223:4–7, 313:1–12.
[37] Ex. 49, Dep. of Scott Fishman at 287:16–21, 290:17–12.
[38] Ex. 4, Dep. of Russell Portenoy at 398:21–399:2.

influenced to say things I did not believe."[39] On this record, Plaintiffs have not carried their burden to show that the Manufacturers directed or controlled the KOLs.

Plaintiffs' case with respect to the third-party healthcare organizations is similarly unsupported by record evidence. Plaintiffs and their experts had the benefit of extensive discovery of the Manufacturers, but, again, all they uncovered was the Manufacturers' independent financial relationships with these organizations. But Plaintiffs' speculation that money must have forced these organizations to bend to the direction of the Manufacturers is unsupported by any evidence.

B. There Is No Evidence of a Supply Chain Enterprise.

As to the "Supply Chain Enterprise," Plaintiffs envision an *ad hoc* association between Manufacturers and Distributors with a "common purpose" to increase opioid shipments. According to Plaintiffs, Manufacturers and Distributors failed to report suspicious orders and failed to prevent diversion. Plaintiffs allege the Supply Chain Enterprise associates coordinated their plans during meetings of the Healthcare Distribution Alliance (HDA). But, again, there is ***no evidence***, let alone legally sufficient evidence, of any unlawful coordination or agreement. There is only the benign fact that a trade association provided the opportunity for Manufacturers and Distributors to network. This is not enough. *Cf. Am. Dental Ass'n*, 605 F.3d at 1295–96. Trade associations serve valuable and legitimate commercial purposes, and mere attendance does not turn Manufacturers and Distributors into a RICO enterprise with a common unlawful purpose. *See generally Maple Flooring Manu. Ass'n v. United States*, 268 U.S. 563, 584 (1925).

As with the purported Marketing Enterprise associates, Plaintiffs have failed to produce ***any*** evidence of fraudulent coordination amongst the Supply Chain associates, during HDA meetings or otherwise. Rather, the evidence shows nothing more than a series of ***separate*** and

[39] Ex. 21, Decl. of Russell Portenoy, M.D. ¶ 35.

independent business relationships between individual entities. Because Plaintiffs have not produced any evidence that the Manufacturers' reporting practices were anything more than parallel conduct, the Supply Chain Enterprise claims fail.

II. THERE IS NO EVIDENCE OF A CONSPIRACY BETWEEN COMPETING MANUFACTURERS.

Plaintiffs allege the multiple independent and competitor Manufacturers were members of conspiracies that violated Ohio law and §1962(d) of RICO. But they have not produced any evidence to support these claims. "Under Ohio law, a claim for civil conspiracy requires 'a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages.'" *Burgess v. Fischer*, 735 F.3d 462, 483 (6th Cir. 2013) (quoting *Kenty v. Transamerica Prem. Ins. Co.*, 650 N.E.2d 863, 866 (Ohio 1995)). To establish a RICO conspiracy, Plaintiffs must show "the existence of an illicit agreement to violate the substantive RICO provision." *Grubbs v. Sheakley Grp., Inc.*, 807 F.3d 785, 805–06 (6th Cir. 2015) (quoting *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 411 (6th Cir.2012)). Plaintiffs must show that any alleged conspirators "at least have a 'single-mindedness to achieve a particular goal.'" *United States v. Pinson*, 860 F.3d 152, 162 (4th Cir. 2017). There can be no conspiracy where "the cast of characters [is] of at least two minds, if not more." *Id.* Plaintiffs' alleged conspiracy involving many different types of Manufacturers selling many different types of opioids at different times in a competitive market over a twenty-year period makes no sense—and lacks any evidentiary support. And there is certainly no evidence of any marketing-based conspiracy that involves Manufacturers of generic medicines, which do not market or promote the safety, efficacy, or therapeutic value of those medicines directly or through third parties.

Just as Plaintiffs have not adduced any evidence of the coordination required to establish an enterprise, they also have no legally sufficient evidence of an ***agreement*** to participate in the pattern of racketeering activity (through an enterprise or otherwise), as required to show a conspiracy to violate RICO under § 1962(d). Nor can Plaintiffs show a "malicious combination" to violate the law, as required to establish a civil conspiracy. At most, they can show only independent decisions by certain Manufacturers to sponsor third parties or to market their own prescription opioid medication—in other words, behavior "just as consistent with independent conduct as it is with a conspiracy." *Hensley v. Gassman*, 693 F.3d 681, 695 (6th Cir. 2012) (affirming summary judgment on conspiracy claim); *see also Woodward Const., Inc. v. For 1031 Summit Woods, L.L.C.*, 30 N.E. 3d 237, 244 (Ohio Ct. App. 2015) ("Supposition alone . . . is not sufficient to make a case for civil conspiracy.").

Because the Sixth Circuit has refused to allow "mere conjecture and speculation" to substitute for "proof of an unlawful agreement," *Regets v. City of Plymouth*, 568 F. App'x 380, 391 (6th Cir. 2014), Plaintiffs have failed to create a genuine issue of material fact as to their RICO, OCPA, and civil conspiracy claims. Additionally, to the extent that Plaintiffs' conspiracy claims seek to impose liability on any Manufacturer based solely on evidence of its lawful associations with other Manufacturers or with KOLs, healthcare organizations, Distributors, the PCF, or the HDA, their claims violate the First Amendment: "liability cannot, consistent with the First Amendment, be imposed upon mere associations." *We, Inc. v. City of Phila.*, 174 F.3d 322, 329 (3d Cir. 1999).

III. PLAINTIFFS HAVE FAILED TO ESTABLISH CAUSATION OR A RICO/OCPA INJURY.

Plaintiffs must produce admissible and sufficient evidence that they were "injured . . . by reason of" a RICO or OCPA violation. 18 U.S.C. § 1964(c). When ruling on the motion to

dismiss, the Court found it "plausible that Plaintiffs' asserted injuries were directly caused 'by reason of' Defendants' injurious conduct." Op. (Dkt. 1203) at 12. But fact and expert discovery did not provide evidence of the necessary causal link. First, Plaintiffs fail as a matter of law to show there is a causal connection between the alleged RICO conduct and Plaintiffs' damages. Second, Plaintiffs cannot maintain a RICO or OCPA claim for Manufacturers' branded promotional activities that were competitive in nature, and not in furtherance of the alleged enterprises. Finally, at a minimum Plaintiffs cannot recover damages that directly resulted from personal injuries to citizens.

A. Plaintiffs Cannot Establish Causation.

Plaintiffs impermissibly seek to recover indirect damages flowing from injuries allegedly suffered by third parties who became addicted to or overdosed on lawful and illicit opioids, Ohioans whose property values decreased, foster children, or victims of purported "opioid-related" crimes. To show that Plaintiffs suffered injury "by reasons of" a RICO or OCPA violation, they must satisfy traditional but-for and proximate cause requirements. Plaintiffs can satisfy neither. Like all their claims, Plaintiffs' RICO and OCPA claims rely on the faulty econometric analyses of Drs. Rosenthal and Cutler, as well as an insurmountably attenuated causal chain. *See* Mfrs.' Br. Mot. Summ. J. re: Causation. In its Order on the Manufacturers' Motion to Dismiss, this Court suggested Plaintiffs might be able to shorten this causal chain by showing that the "RICO Marketing Defendants made deceptive claims in promoting their opioids in order to sell more opioids than the legitimate medical market could support," and "the excess opioids . . . were then diverted into an illicit, black market." Op. at 9–10. Plaintiffs tried to take the Court's suggestion, but as explained in the Manufacturers' Causation Brief, that causal chain is unsupported by the evidence. The Manufacturers incorporate those arguments here.

The requirement of proximate cause further limits the reach of RICO and OCPA. Plaintiffs cannot recover for indirect injuries because "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors." *Holmes v. Secs. Inv. Prot. Corp.*, 503 U.S. 258, 269 (1992). It is impossible to determine whether any damages were caused by the Manufacturers' alleged racketeering acts, as opposed to ***independent conduct by each Manufacturer or other industry actors***, ***or other actors in the causal chain***. (*See* Mfrs.' Br. Mot. Summ. J. re: Causation); *see also Saro v. Brown*, 11 F. App'x 387, 389 (6th Cir. 2001) ("A plaintiff cannot allege merely that an act of racketeering occurred and that he suffered. He must show a causal connection between his injury and a predicate act."); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 327–28 (E.D.N.Y. 2014), *aff'd*, 806 F.3d 71 (2d Cir. 2015). Plaintiffs' overreaching and novel theory that they are entitled to RICO damages also depends on indirect third-party injuries and numerous intervening actors. *See, e.g.*, *City of Cleveland v. Ameriquest Mortg. Secs., Inc.*, 615 F.3d 496, 499–500 (6th Cir. 2010); *Sidney Hillman Health Ctr. of Rochester v. Abbot Labs.*, 873 F.3d 574, 578 (7th Cir. 2017); *see also Wethington v. Purdue Pharma L.P.*, 218 F.R.D. 577, 589 (S.D. Ohio 2003). Plaintiffs' alleged injuries are premised on services allegedly rendered to third parties injured by the opioid abuse crisis. *See* Mfrs.' Br. Mot. Dismiss at 13–14. Although this Court decided Plaintiffs could attempt to marshal proof of a causal chain that did not involve physicians' intervening prescribing decisions, Op. at 9–10, their experts have chosen to use a damages model that depends on those decisions. Moreover, Plaintiffs seek to hold the Manufacturers liable for the actions of third-party criminal gangs who sold illegal heroin and fentanyl in Summit and Cuyahoga. Plaintiffs offer nothing but their own say-so that this criminal third-party conduct was "foreseeable" and the allegedly resulting injuries "direct."

Finally, as explained in Manufacturers' Motion to Exclude Meredith Rosenthal's Opinions and Proposed Testimony, Professor Rosenthal never attempts to measure or isolate the impact of the KOLs or medical organizations. As a result, there is no way for this Court or a jury to know what was caused by the alleged racketeering, as opposed to other factors. Plaintiffs have not created a genuine issue of material fact as to but-for or proximate cause.

B. RICO or OCPA Damages Are not Available for the Manufacturers' Branded Marketing Activities.

Plaintiffs can only recover damages caused "by reason of a ***violation of section 1962***." 18 U.S.C. § 1964(c) (emphasis added). A person violates RICO only if it "conducted or participated in the conduct of the '***enterprise's*** affairs,' not just their ***own*** affairs." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993) (emphasis in original). Branded marketing—each Manufacturer's efforts to sell its own particular brand of prescription medication—was not conducted through any "enterprise" with other Manufacturers, KOLs, or healthcare organizations. *See Sedima S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 495 (1985). Instead, it was the independent action of a Manufacturer trying to gain sales at the expense of other Manufacturers. This is not a RICO violation; it is competition.

Plaintiffs thus cannot pursue a RICO or OCPA claim for injuries allegedly caused by the Manufacturers' branded marketing activities, such as detailing, because the injuries could not have been caused by any purported RICO or OCPA violations. The "violation" is a pattern of racketeering activity committed through an enterprise. Plaintiffs have not shown that the Manufacturers' branded marketing activities were part of any pattern perpetrated through either alleged enterprise. At a minimum the Court should enter judgment for the Manufacturers on the racketeering claims to the extent they depend on branded marketing.

C. The Court Should Dismiss the RICO/OCPA Damages That Result From Injuries to Third Parties.

In *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, the Sixth Circuit held that "personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under §1964(c)." 731 F.3d 556, 565-66 (6th Cir. 2013); *see also Perry v. Am. Tobacco Co., Inc.*, 324 F.3d 845, 849 (6th Cir. 2003) (citing *Laborers Loc. 17 Health & Benefits Fund v. Phillip Morris, Inc.*, 191 F.3d 229, 237 (2d Cir. 1999) ("[C]ourts have held that plaintiffs who are obligated to pay the medical expenses of another may not recover against the tortfeasor who caused the damage.")). In its Opinion and Order denying the Manufacturers' motion to dismiss, this Court declined to decide which categories of alleged damages "arise directly out of the personal injury of the citizens." Op. at 16. The Court commented, however, that healthcare costs to treat addiction and overdose and emergency responses to addiction could effectively be "claims to recoup the costs of medical expenses." *Id.* The Court now has the benefit of Plaintiffs' expert reports, and can determine the categories of claimed damages that result from personal injuries to County residents.

When estimating damages, Plaintiffs' expert Professor Thomas McGuire identified a number of allegedly "affected divisions," some of which spent money or provided services to respond to addiction or provide healthcare to county citizens. In Cuyahoga County:

- The Alcohol, Drug Addiction and Mental Health Services (ADAMHS) Board funded services to treat mental health and substance-addiction problems.[40]
- The Division of Children and Family Services (DCFS) provided services to children at risk of abuse or neglect.[41]
- The Sheriff's Office responded to opioid overdoses.[42]

[40] Ex. 50, Rep. of Prof. Thomas McGuire (Damages to Bellwethers), ¶ 52.
[41] *Id.*
[42] *Id.* ¶¶ 45, 52.

- The County Medical Examiner's office investigated deaths due to opioid use.[43]

In Summit County:

- The Alcohol, Drug Addiction and Mental Health Services Board (ADM) funded mental health and substance-addiction treatment and prevention services.[44]
- The Children Services Board provided abuse and neglect assessments.[45]
- The Sheriff's Office responded to opioid overdoses.[46]
- The County Jail provided mental health and medical treatment.[47]
- The County Medical Examiner's office investigated unexpected deaths.[48]

The costs allegedly incurred by these agencies all "flow from" (indeed, directly result from) personal injuries to county citizens. As a result, consistent with *Jackson* and *Perry*, Plaintiffs cannot pursue RICO or OCPA claims for those costs.

When ruling on the motion to dismiss, this Court suggested that the broadest reading of Sixth Circuit precedent might permit recovery for any costs that "go beyond the ordinary cost of providing services" and are attributable to unlawful conduct. Op. at 20. Manufacturers respectfully urge the Court to follow the "more restrictive reading of *Jackson*," *id.*, and the dozens of other courts that have prohibited recovery of damages flowing from third-party personal injuries.

[43] *Id.* ¶¶ 49, 52.
[44] *Id.* ¶54.
[45] *Id.*
[46] *Id.* ¶¶ 45, 54.
[47] *Id.* ¶ 54.
[48] *Id.* ¶ 54.

CONCLUSION

Plaintiffs have failed to create a genuine issue of fact as to their RICO, OCPA, and conspiracy claims. The Court should enter judgment for the Manufacturers on Counts I, II, III, IV, and XI.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Lindsey Cohan, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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